UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

February 2022

Commission File Number: 0001723069

Tiziana Life Sciences LTD

(Exact Name of Registrant as Specified in Its Charter)

9th Floor
107 Cheapside
London
EC2V 6DN
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On February 4, 2022, Tiziana Life Sciences LTD (the "Company") issued a news service announcement in the United States announcing the Submission of Amendment to Investigational New Drug Application to Advance Oral Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, in Patients with Crohn's Disease.

The Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TIZIANA LIFE SCIENCES LTD

Date: February 4, 2022

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	News Service Announcement, dated February 4, 2022

Exhibit 99.1

Tiziana Announces Submission of Amendment to Investigational New Drug Application to Advance Oral Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, in Patients with Crohn's Disease

- Tiziana is Developing the First Oral Form of Foralumab in a Convenient Capsule to be Evaluated in Phase 1b Clinical Study

New York, February 4, 2022 – Tiziana Life Sciences Ltd (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company enabling breakthrough immunotherapies via novel routes of drug delivery, today announced submission of an amendment to an Investigational New Drug (IND) application for evaluation of orally administered capsules of foralumab, which it believes would be the first "take home" immunotherapy, in patients with mild-to-moderately active Crohn's Disease. If accepted by the U.S. Food and Drug Administration (FDA), the amendment is expected to expedite patient enrollment and completion of the foralumab Phase 1b study by the fourth quarter of 2022.

The currently planned Phase 1b study with an amended protocol is designed as a placebo-controlled, randomized and dose-escalating trial, in mild-to-moderate patients with Crohn's Disease. The patients will be dosed up to 5 mg once daily for five consecutive days and safety of patients will be monitored throughout the treatment period in the hospital or clinical research unit (CRU). The primary objective of this study is to determine safety and tolerability. The study will also evaluate the pharmacodynamic (PD) effects on modulation of immunobiomarkers, including calprotectin, a widely used biomarker for gut inflammation, in stools, as a secondary endpoint. Data from an earlier Phase 1a, single-ascending dose (SAD) study with orally administered foralumab in healthy volunteers determined that the treatment was well-tolerated up to 5 mg, which was the highest dose tested.

This amendment would allow for the investigation of a broader patient population as well as a shorter dosing period. Previously, Tiziana had submitted an IND to conduct a Phase 1b study in moderate-to-severe active Crohn's Disease patients to evaluate safety of enteric-coated foralumab capsules administered orally once daily for 14 days as an inpatient study in the hospital or CRU with safety monitoring, for which the FDA issued a 'Study May Proceed letter'. However, initial feasibility findings indicated that enrollment of patients in this initial safety study, requiring 14-day hospitalization, was highly challenging due to the COVID-19 pandemic. Thus, the clinical protocol has been amended to expedite patient enrollment and study completion.

The clinical findings from this Phase 1b study could support moving foralumab into a Phase 2 clinical trial in patients with mild-to-moderate Crohn's Disease. Tiziana is awaiting FDA's comments on the amended TILS-014 protocol and, with clearance of the amendment, anticipates completing the Phase 1b study by the fourth quarter of 2022.

Dr. Kunwar Shailubhai, Chief Executive Officer of Tiziana noted, "Current immunotherapies for treatment of Crohn's disease, including ulcerative colitis, are administered either intravenously or subcutaneously. In this clinical study, foralumab would be formulated as a novel, convenient, 'take home' immunotherapy in an oral capsule form. Thus, submission of this IND amendment marks an important step towards advancing our novel approach as well as validating the local mode of action of foralumab to potentially treat Crohn's Disease and other inflammatory bowel diseases".

About Foralumab

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, shows reduced release of cytokines after IV administration in healthy volunteers and in patients with Crohn's disease. In a humanized mouse model (NOD/SCID IL2γc-/-), it was shown that whilst targeting the T cell receptor, orally administered foralumab modulates immune responses of the T-cells and enhances regulatory T-cells (Tregs) and thus provides therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy (Ogura M. et al., 2017. Clin Immunol.183:240-246). Once a day treatment for 10 consecutive days with intranasal foralumab was not only well tolerated but it also produced strong clinical responses in COVID-19 patients (Moreira et al., 2021. Front Immunol. 2021; 12: 709861). Based on these studies, the intranasal and oral administration of Foralumab offers the potential to become a well-tolerated immunotherapy for autoimmune and inflammatory diseases by the induction of Tregs.

About Tiziana Life Sciences Ltd

Tiziana Life Sciences is a clinical-stage biopharmaceutical company developing breakthrough therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy. Tiziana's innovative nasal, oral and inhalation approaches in development have the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's two lead candidates, intranasal foralumab, the only fully human anti-CD3 mAb, and milciclib, a pan-CDK inhibitor, have both demonstrated a favorable safety profile and clinical response in patients in studies to date. Tiziana's technology for alternative routes of immunotherapy has been patented with several applications pending and is expected to allow for broad pipeline applications.

Forward-Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward-looking statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections about its industry; its beliefs; and assumptions. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,' 'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the Company's control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. The Company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of the Company only as of the date of this announcement. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. The Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

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